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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/634,641 | 08/04/2003 | Kyoya Takahata | TECH-004 | 7194 |
| 24353 | 7590 | 07/13/2005 | EXAMINER | |
| BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303 | | | DELACROIX MUIRHEI, CYBILLE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 10/634,641 | Applicant(s) TAKAHATA, KYOYA | |
| | Examiner Cybille Delacroix-Muirheid | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005 and 20 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 15-22 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

The following is responsive to applicant's amendment received April 6, 2005 and the declaration received April 20, 2005.

Claims 12-14 are cancelled. New claims 15-22 are added. Claims 1-11, 15-22 are currently pending.

The previous objection of claim 11 set forth on page 2 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous rejection of claims 13-14 under 35 USC 112/101, set forth in paragraph 1 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous rejection of claims 11-14 under 35 USC 102(a) or (b) over Jin et al., set forth at paragraph 2 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(a) or 102(b) over Takahata et al., set forth in paragraph 6 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment, declaration (*Katz* declaration) and remarks contained therein.

The previous claim rejection under 35 USC 103(a) over Takahata et al., set forth in paragraph 8 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment, declaration (*Katz* declaration) and remarks contained therein.

The previous claim rejection under 35 USC 103(a) over Martin et al., 2004/0122089, set forth in paragraph 7 of the office action mailed Oct. 6, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing (1) the previous rejection of claims 1-2, 5, 9-10 under 35 USC 102(a) or (b) over Jin et al. (§ 2 of the office action mailed Oct. 6, 2004); (2) the previous claim rejection under 35 USC 102(b) over Janusz et al. (journal) or Janusz et al. 4,898,887 (§ 3 of the office action mailed Oct. 6, 2004); (3) the previous claim rejection under 35 USC 102(e) over Martin et al., 2004/0122089 (§ 4 of the office action mailed Oct. 6, 2004); and (4) the previous claim rejection under 35 USC 102(b) over Chen, 5,221,692 (§ 5 of the office action mailed Oct. 6, 2004), have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Oct. 6, 2004 with the following additional comment.

Rejection of claims 1-2, 5, 9-10 under 35 USC 102(a) or (b) over Jin et al.:

Applicant argues that Jin et al. do not disclose or suggest a composition that induces apoptosis in leukemia or melanoma cells and therefore do not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims.

Said arguments have been considered but are not found to be persuasive.

Applicant's arguments pertain to the intended use of compounds already disclosed in the prior art. Jin et al. teach applicant's claimed compound. Intended use is given no patentable weight unless it results in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the

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intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully maintains that Jin's compound, which anticipates the claims, is capable of use as anti-tumor or anti-melanoma agents. Additionally, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Please MPEP 2112.01. Since Jin teaches an identical compound, i.e. dohevanil, then the claimed anti-melanoma and anti-leukemia properties are necessarily present.

It is for these reasons the rejection is maintained.

Rejection of claims 1-2, 5-6, 7-8 under 35 USC 102(b) over Janusz et al., (journal) or Janusz et al., 4,898,887:

Applicant contends that neither of the Janusz et al. references discloses or suggests a composition that induces apoptosis in leukemia or melanoma cells. Therefore Janusz et al. (journal) or Janusz et al., '887 do not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims.

Said arguments have been considered but are not found to be persuasive.

Applicant's arguments pertain to the intended use of compounds already disclosed in the prior art. Both Janusz et al. references teach applicant's claimed compounds. Intended use is given no patentable weight unless it results in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully maintains that the compounds disclosed by Janusz et

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al. (journal or patent), which anticipate the claims, are capable of use as anti-tumor or anti-melanoma agents. Additionally, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Please MPEP 2112.01. Since both Janusz et al. references teach identical compounds, then the claimed anti-melanoma and anti-leukemia properties are necessarily present.

It is for these reasons the rejection is maintained.

Rejection of claims 1-2, 5-6 under 35 USC 102(e) over Martin et al., 2004/0122089:

Applicant argues that Martin et al. do not disclose or suggest a composition that induces apoptosis in leukemia or melanoma cells and therefore do not describe an “anti-leukemia” or an “anti-melanoma” composition as recited in the present claims. At best, Martin et al. disclose that arvanil has an anti-proliferative effect on human breast cancer cells and further discloses analgesic compositions.

Said arguments have been considered but are not found to be persuasive.

Applicant's arguments pertain to the intended use of a compound already disclosed in the prior art. Martin et al. teach applicant's claimed compound. Intended use is given no patentable weight unless it results in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully maintains that Martin's compound, which anticipates the claims, is capable of use as anti-tumor or anti-melanoma agents. Additionally, if the prior art teaches the

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identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Please MPEP 2112.01. Since Martin et al. teach an identical compound, i.e. arvanil, then the claimed anti-melanoma and anti-leukemia properties are necessarily present.

It is for these reasons the rejection is maintained.

Rejection of claims 1-2, 5-7 under 35 USC 102(b) over Chen 5,221,692:

Applicant argues that Chen does not disclose or suggest a composition that induces apoptosis in leukemia or melanoma cells and therefore do not describe an "anti-leukemia" or an "anti-melanoma" composition as recited in the present claims. Instead, applicant argues Chen discloses that olvanil has activity as an anti-inflammatory analgesic agent.

Said arguments have been considered but are not found to be persuasive.

Applicant's arguments pertain to the intended use of compounds disclosed in the prior art. Chen teaches applicant's claimed compound. Intended use is given no patentable weight unless it results in a structural difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). In this case, the Examiner respectfully maintains that Chen's compound, which anticipates the claims, is capable of use as anti-tumor or anti-melanoma agents. Additionally, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily

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present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Please MPEP 2112.01. Since Chen teaches an identical compound, i.e. olvanil, then the claimed anti-melanoma and anti-leukemia properties are necessarily present.

It is for these reasons the rejection is maintained.

Allowable Subject Matter

Claims 11, 15-22 are free from the prior art because the prior art does not disclose or fairly suggest the claimed method of treating melanoma or leukemia in a patient by administering to the patient a compound of Formula (1).

Conclusion

Claims 1-2, 5-10 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
July 6, 2005


RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614